

## § 1.485a

individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, any VA employee making an oral disclosure under authority of this section shall make an accounting of the disclosure in accordance with the Privacy Act (5 U.S.C. 552a(c) and 38 CFR 1.576(c)) and document the disclosure in the patient's records setting forth in writing:

(1) The name and address of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure;

(4) The nature of the emergency (or error, if the report was to FDA);

(5) The information disclosed; and

(6) The authority for making the disclosure (§ 1.485 of this part).

(Authority: 38 U.S.C. 7332(b)(2)(A))

## § 1.485a Eye, organ and tissue donation.

A VHA health care facility may disclose the individually-identified medical record information of an individual covered by §§ 1.460 through 1.499 of this part to an authorized representative of a procurement organization for the purpose of facilitating determination of whether the individual is a suitable potential organ, eye, or tissue donor if:

(a) The individual is currently an inpatient in a VHA health care facility;

(b) The individual is, in the clinical judgment of the individual's primary health care provider, near death or deceased;

(c) The VHA health care facility has a signed agreement with the procurement organization in accordance with the applicable requirements of the United States Department of Health and Human Services (HHS); and

(d) The VHA health care facility has confirmed with HHS that it has certified or recertified the organ procurement organization as provided in the

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applicable HHS regulations. VA medical centers must verify annually in January of each calendar year with the Food and Drug Administration (FDA) that an eye bank or tissue bank has complied with the FDA registration requirements of 21 CFR part 1271 and that the registration status is active before permitting an eye bank or tissue bank to receive protected health information.

(Authority: 38 U.S.C. 5701(k), 7332(b)(2)(E))

[72 FR 48242, Aug. 23, 2007, as amended at 73 FR 65260, Nov. 3, 2008]

## § 1.486 Disclosure of information related to infection with the human immunodeficiency virus to public health authorities.

(a) In the case of any record which is maintained in connection with the performance of any program or activity relating to infection with the HIV, information may be disclosed to a Federal, State, or local public health authority, charged under Federal or State law with the protection of the public health, and to which Federal or State law requires disclosure of such record, if a qualified representative of such authority has made a written request that such record be provided as required pursuant to such law for a purpose authorized by such law. In the case of a State law, such law must, in order for VA to be able to release patient name and address information in accordance with 38 U.S.C. 5701(f)(2), provide for a penalty or fine or other sanction to be assessed against those individuals who are subject to the jurisdiction of the public health authority but fail to comply with the reporting requirements.

(b) A person to whom a record is disclosed under this section may not re-disclose or use such record for a purpose other than that for which the disclosure was made.

(Authority: 38 U.S.C. 7332(b)(2)(C))

## § 1.487 Disclosure of information related to infection with the human immunodeficiency virus to the spouse or sexual partner of the patient.

(a) Subject to paragraph (b) of this section, a physician or a professional counselor may disclose information or

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records indicating that a patient is infected with the HIV if the disclosure is made to the spouse of the patient, or to an individual whom the patient has, during the process of professional counseling or of testing to determine whether the patient is infected with such virus, identified as being a sexual partner of such patient.

(b) A disclosure under this section may be made only if the physician or counselor, after making reasonable efforts to counsel and encourage the patient to provide the information to the spouse or sexual partner, reasonably believes that the patient will not provide the information to the spouse or sexual partner and that the disclosure is necessary to protect the health of the spouse or sexual partner.

(c) A disclosure under this section may be made by a physician or counselor other than the physician or counselor referred to in paragraph (b) of this section if such physician or counselor is unavailable by reason of extended absence or termination of employment to make the disclosure.

(Authority: 38 U.S.C. 7332(b))

### § 1.488 Research activities.

Subject to the provisions of 38 U.S.C. 5701, 38 CFR 1.500–1.527, the Privacy Act (5 U.S.C. 552a), 38 CFR 1.575–1.584 and the following paragraphs, patient medical record information covered by §§1.460 through 1.499 of this part may be disclosed for the purpose of conducting scientific research.

(a) Information in individually identifiable form may be disclosed from records covered by §§1.460 through 1.499 of this part for the purpose of conducting scientific research if the Under Secretary for Health or designee makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research.

(2) Has a research protocol under which the information:

(i) Will be maintained in accordance with the security requirements of §1.466 of this part (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section.

(3) Has furnished a written statement that the research protocol has been reviewed by an independent group of three or more individuals who found that the rights of patients would be adequately protected and that the potential benefits of the research outweigh any potential risks to patient confidentiality posed by the disclosure of records.

(b) A person conducting research may disclose information obtained under paragraph (a) of this section only back to VA and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

(Authority: 38 U.S.C. 7332(b)(2)(B))

### § 1.489 Audit and evaluation activities.

Subject to the provisions of 38 U.S.C. 5701, 38 CFR 1.500–1.527, the Privacy Act (5 U.S.C. 552a), 38 CFR 1.575–1.584, and the following paragraphs, patient medical records covered by §§1.460 through 1.499 of this part may be disclosed outside VA for the purposes of conducting audit and evaluation activities.

(a) *Records not copies.* If patient records covered by §§1.460 through 1.499 of this part are not copied, patient identifying information may be disclosed in the course of a review of records on VA facility premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and:

(1) Where audit or evaluation functions are performed by a State or Federal governmental agency on behalf of VA; or

(2) Who is determined by the VA facility director to be qualified to conduct the audit or evaluation activities.

(b) *Copying of records.* Records containing patient identifying information may be copied by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in §1.466 of this part (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and